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EPAR summary for the public

Matever

levetiracetam

This is a summary of the European public assessment report (EPAR) for Matever. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Matever.

What is Matever?

Matever is a medicine that contains the active substance levetiracetam. It is available as tablets (250 mg, 500 mg, 750 mg and 1000 mg) and as a concentrate that is made up into a solution for infusion (drip into a vein, 100 mg/ml).

Matever is a 'generic medicine'. This means that Matever is similar to a 'reference medicine' already authorised in the European Union (EU) called Keppra. For more information on generic medicines, see the question-and-answer document here.

What is Matever used for?

Matever can be used on its own in patients from 16 years of age with newly diagnosed epilepsy, to treat partial-onset seizures (fits) with or without secondary generalisation. This is a type of epilepsy where too much electrical activity in one side of the brain causes symptoms such as sudden, jerky movements of one part of the body, distorted hearing, sense of smell or vision, numbness, or a sudden sense of fear. Secondary generalisation occurs when the overactivity later reaches the whole brain.

Matever can also be used as an add-on to other anti-epileptic medicines to treat:

- partial-onset seizures with or without generalisation in patients from one month of age;
- myoclonic seizures (short, shock-like jerks of a muscle or group of muscles) in patients from 12 years of age with juvenile myoclonic epilepsy;

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

- primary generalised tonic-clonic seizures (major fits, including loss of consciousness) in patients from 12 years of age with idiopathic generalised epilepsy (the type of epilepsy that is thought to have a genetic cause).

The medicine can only be obtained with a prescription.

How is Matever used?

When Matever is used on its own, the starting dose is 250 mg twice a day, increasing two weeks later to 500 mg twice a day. The dose can be further increased at two-week intervals according to the patient's response, to a maximum dose of 1500 mg twice a day.

When Matever is added to another anti-epileptic treatment, the starting dose in patients over 12 years weighing more than 50 kg is 500 mg twice a day. The daily dose can be increased up to 1500 mg twice a day. In patients aged between six months and 17 years weighing less than 50 kg, the starting dose is 10 mg per kilogram body weight twice a day, which can be increased up to 30 mg/kg twice a day.

Lower doses are used in patients who have problems with their kidneys (such as older patients). Matever tablets are swallowed with liquid. Matever can be given as an infusion using the same doses at the same frequency when using the tablets or the oral solution is not possible. The use of the infusion should be temporary.

How does Matever work?

The active substance in Matever, levetiracetam, is an anti-epileptic medicine. Epilepsy is caused by excessive electrical activity in the brain. The exact way in which levetiracetam works is still unclear but it seems to interfere with a protein called synaptic vesicle protein 2A, which is found in the spaces between nerves and is involved in the release of chemical messengers from nerve cells. This helps Matever to stabilise electrical activity in the brain and prevent seizures.

How has Matever been studied?

Because Matever is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Keppra. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Matever?

Because Matever is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why has Matever been approved?

The CHMP concluded that, in accordance with EU requirements, Matever has been shown to have comparable quality and to be bioequivalent to Keppra. Therefore, the CHMP's view was that, as for Keppra, the benefit outweighs the identified risk. The Committee recommended that Matever be given marketing authorisation.

Other information about Matever

The European Commission granted a marketing authorisation valid throughout the European Union for Matever on 03 October 2011.

The full EPAR for Matever can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Matever, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 08-2011.